

APR 28 2000



K000684

3.0 Summary of Safety and Effectiveness Information:

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700

CONTACT: Angela Silvestri

DEVICE NAME: Synthes Small Fragment Dynamic Compression Locking (DCL) System

DEVICE CLASSIFICATION: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories and 888.3040 Smooth/threaded metallic bone fixation fastener.

PREDICATE DEVICE: Synthes 3.5 mm 90° Cannulated Limited Contact Angled Blade Plates, Synthes Small Reconstruction Plates, Synthes 2.7 mm Reconstruction Plates, and Synthes Small T-Plate.

DESCRIPTION OF DEVICE: The Small Fragment DCL system consists of limited-contact profile plates in straight, reconstruction, Oblique T- and Small T- plates of various sizes and 3.5 mm locking screws. The plates in this system also accept 2.7 mm and 3.5 mm cortex, and 4.0 mm cancellous screws. The plates feature a combination dynamic compression/locking screw hole. The system is available in either stainless steel or titanium.

INDICATIONS: Fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2000

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301-1222

Re: K000684

Trade Name: Small Fragment Dynamic Compression Locking (DCL) System
Regulatory Class: II
Product Code: KTT
Dated: February 25, 2000
Received: February 29, 2000

Dear Ms. Silvestri:

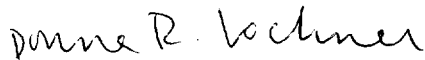
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Celia M. Witten".

 Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



1.0 Indications for Use Statement

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510(k) Number (if known): K000684

Device Name: Synthes (USA) Small Fragment Dynamic Compression Locking (DCL) System

Indications for use:

Fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Donna R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000684